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(54) **PROSTHETIC WRIST IMPLANT**

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This patent is subject to a terminal disclaimer.

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CPC **A61F 2/4261** (2013.01); **A61B 17/86** (2013.01); **A61F 2002/3065** (2013.01);

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(58) **Field of Classification Search**

CPC A61F 2/4261; A61F 2/42; A61F 2002/42;
A61F 2002/4261–2002/4297; A61F
2002/3065; A61F 2002/30652; A61F
2002/30663

USPC 623/21.11–21.17, 19.11–19.14, 16.11,
623/18.11, 19.12, 20.22, 21.13, 21.16

See application file for complete search history.

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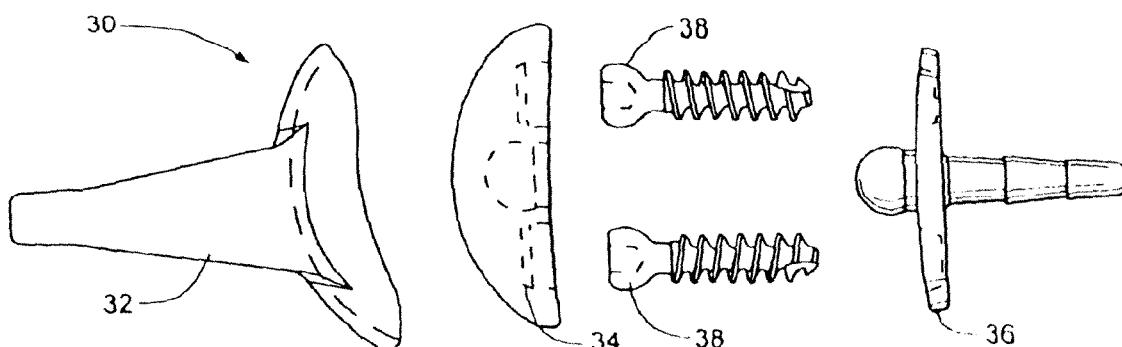
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(57) **ABSTRACT**

A wrist implant requires minimal resection of the distal radius and preserves the sigmoid notch and articulation with the head of the distal ulna. The wrist implant generally includes a radius portion, a carpal portion and a carpal ball. The wrist implant includes a primary articulation and a secondary rotational articulation. The primary articulation occurs between the radius portion and the carpal ball. The secondary articulation occurs between the carpal ball and the carpal portion.

12 Claims, 12 Drawing Sheets



Related U.S. Application Data

continuation of application No. 11/210,416, filed on Aug. 24, 2005, now Pat. No. 7,628,819, which is a division of application No. 10/897,317, filed on Jul. 22, 2004, now Pat. No. 7,625,408.

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A61F 2/30 (2006.01)

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CPC *A61F 2002/30622* (2013.01); *A61F 2002/30654* (2013.01); *A61F 2002/30663* (2013.01); *A61F 2002/30785* (2013.01); *A61F 2002/30904* (2013.01); *A61F 2002/4264* (2013.01); *A61F 2002/4287* (2013.01); *A61F 2002/4631* (2013.01); *A61F 2310/00023* (2013.01); *A61F 2310/00407* (2013.01)

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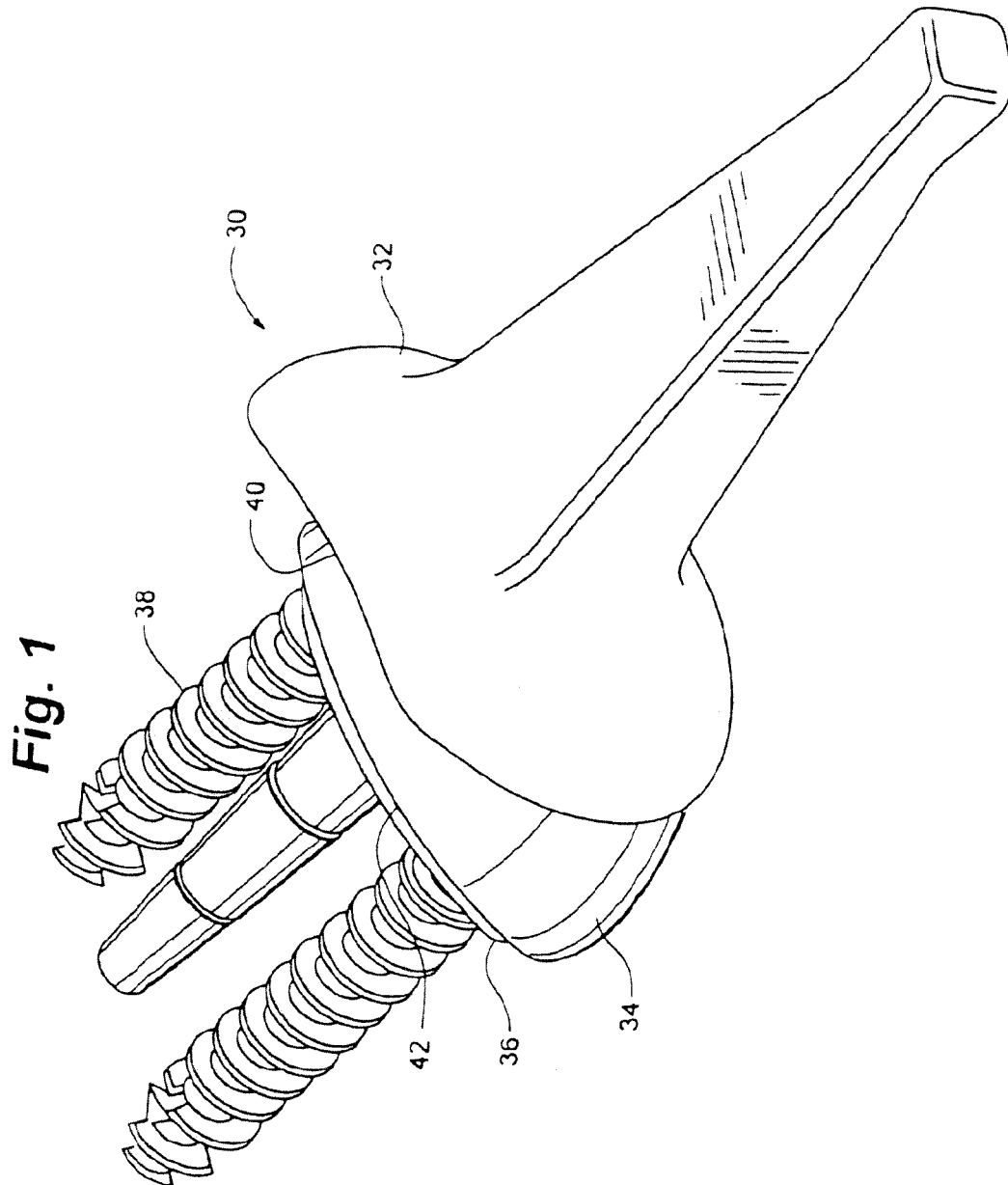
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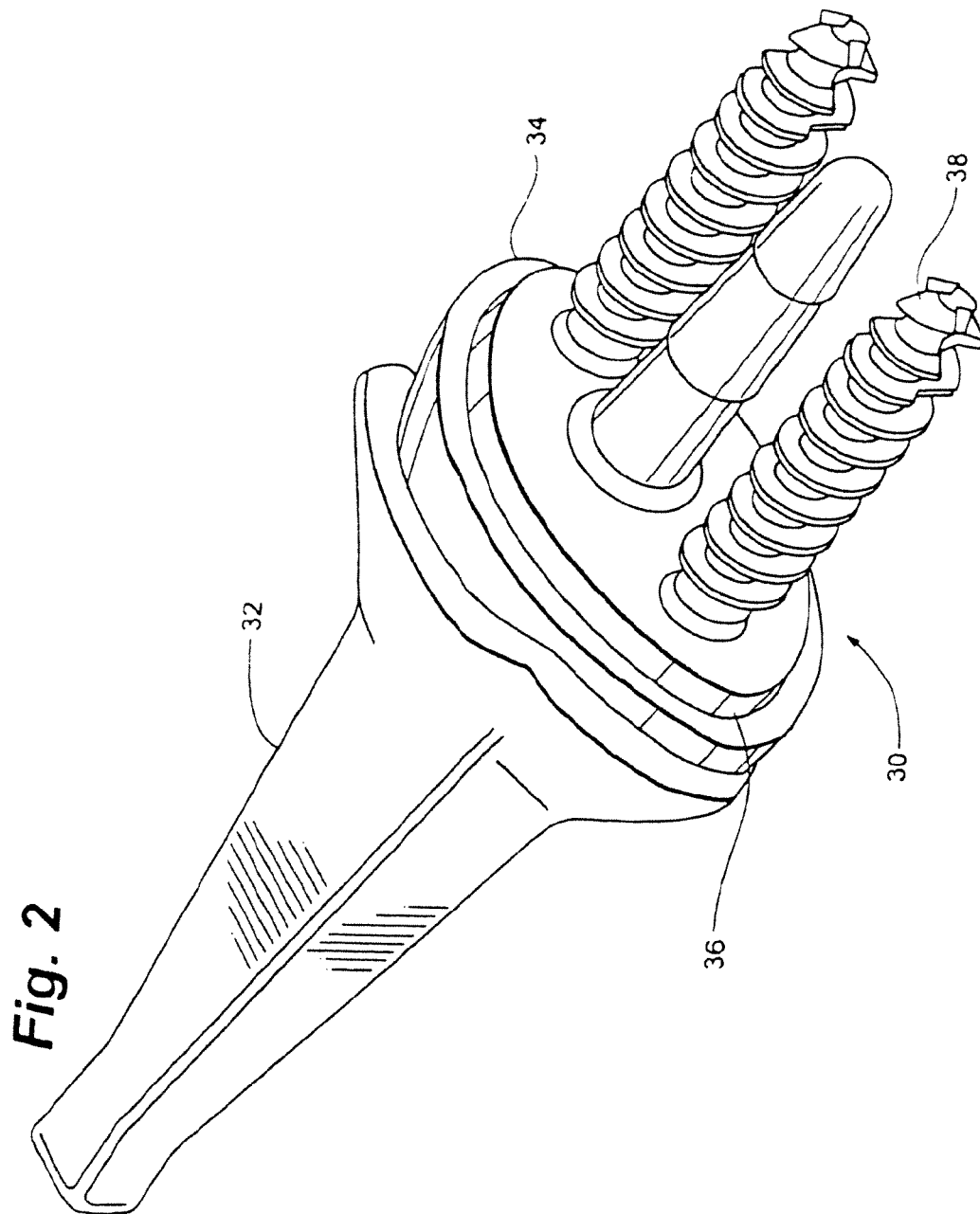
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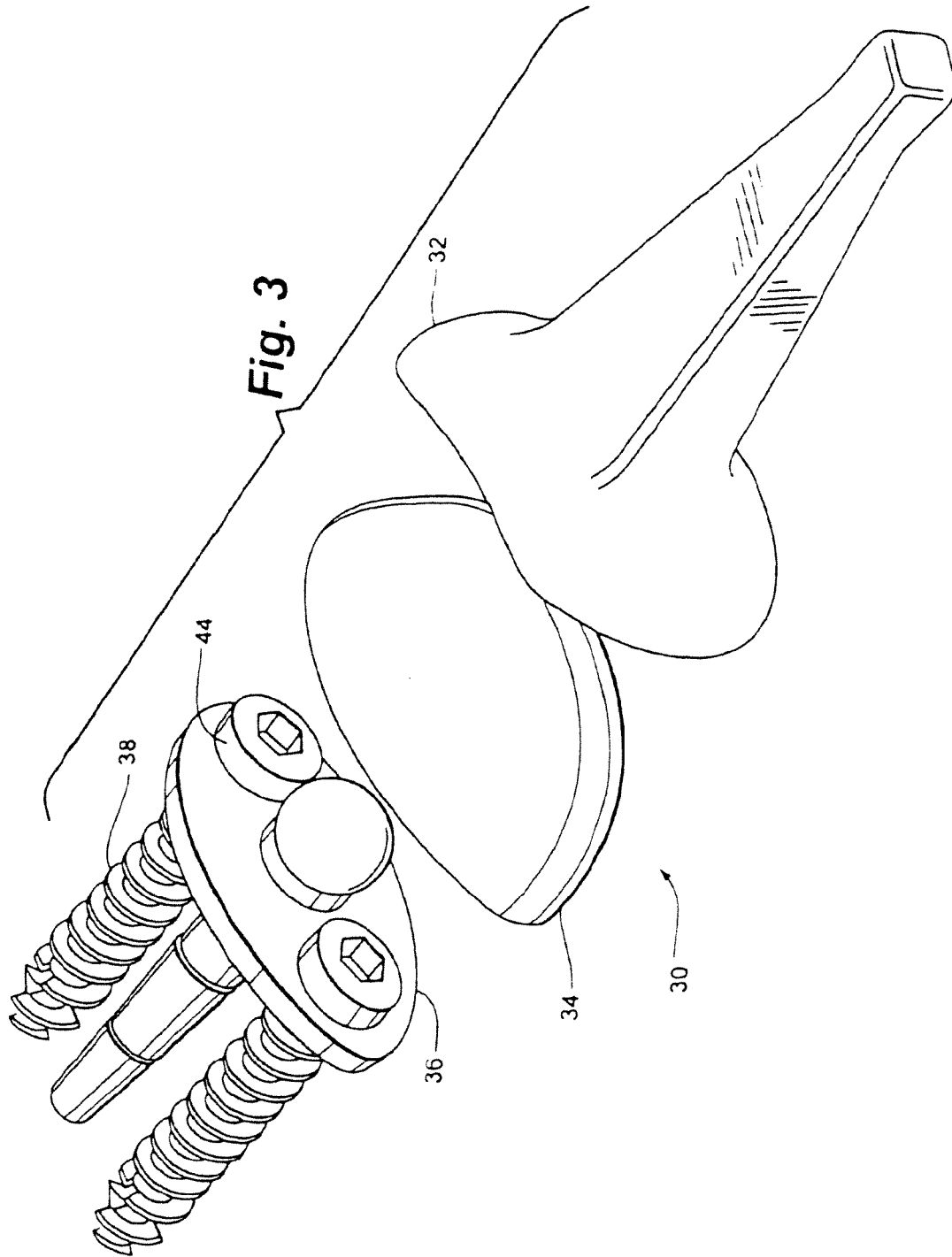
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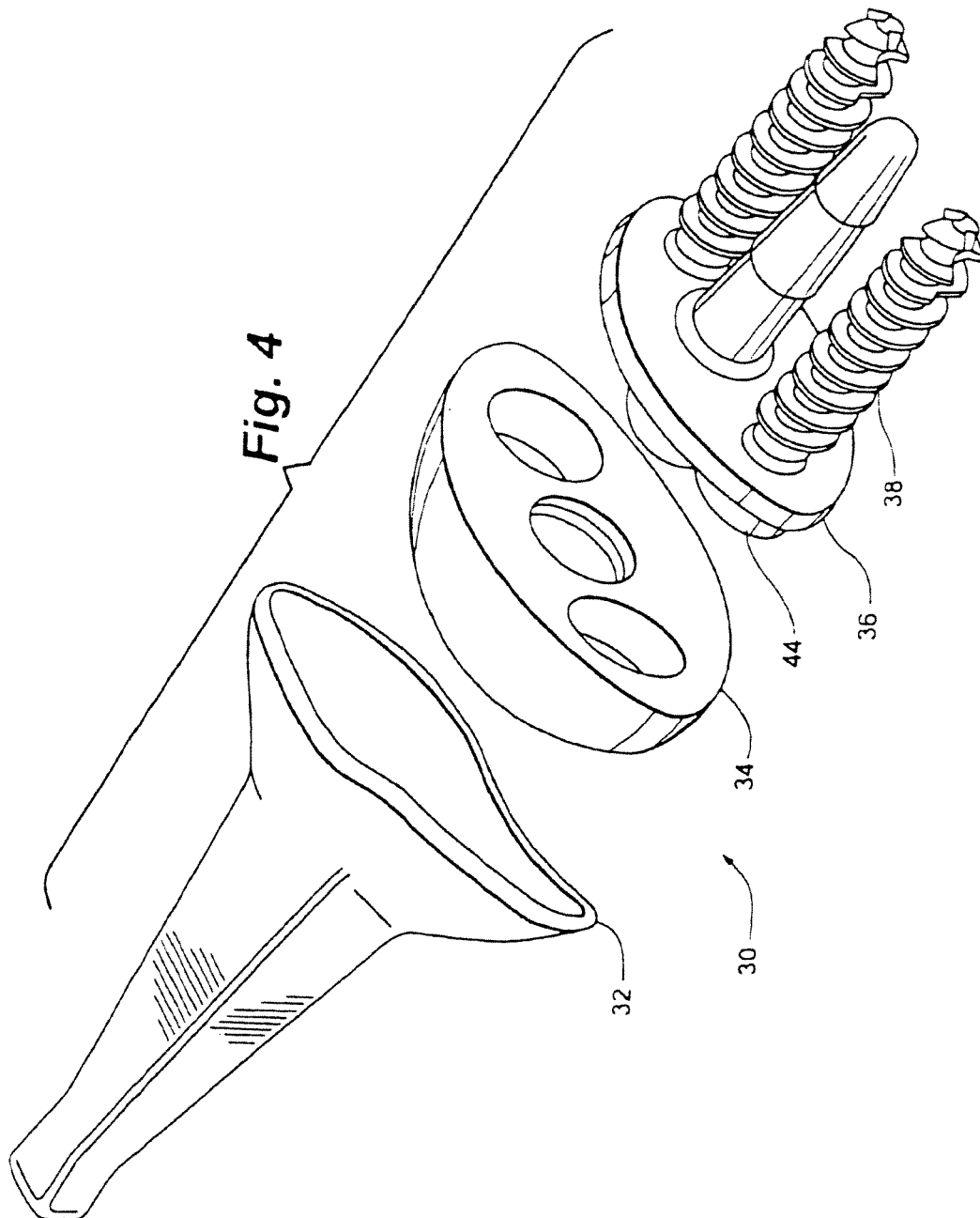
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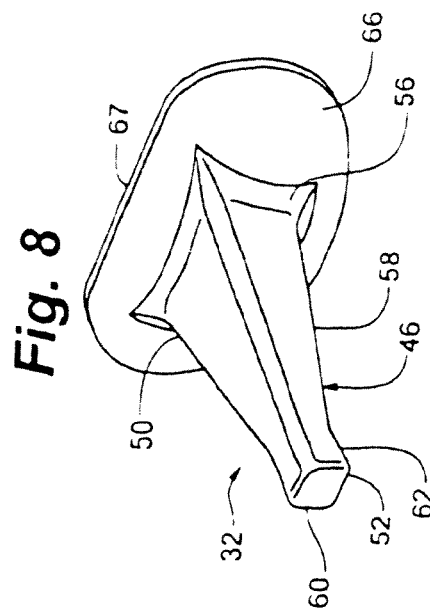
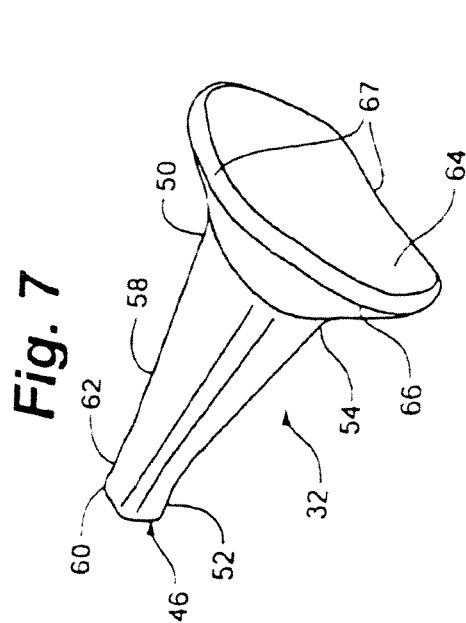
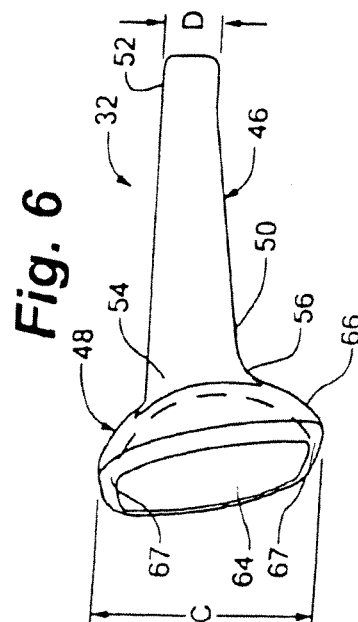
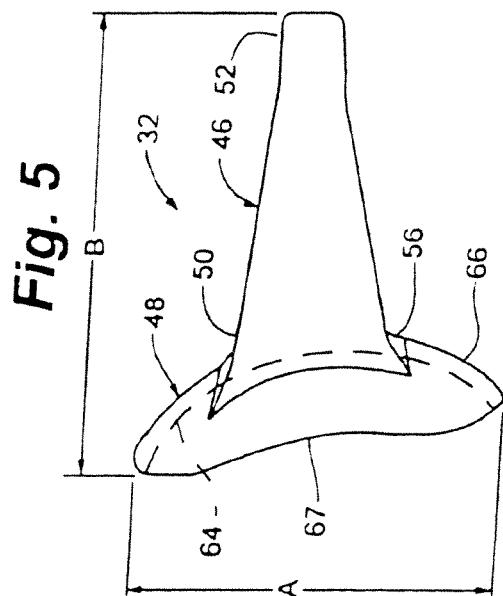


Fig. 9

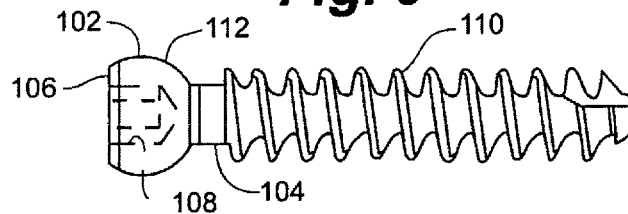


Fig. 10a

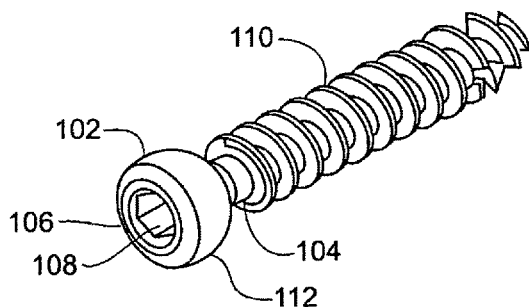


Fig. 10b

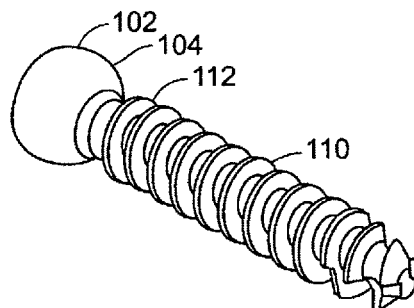


Fig. 11

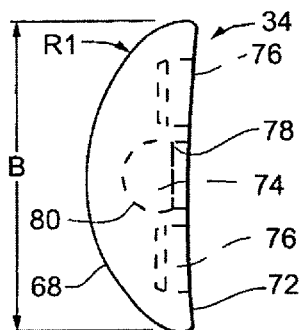


Fig. 12

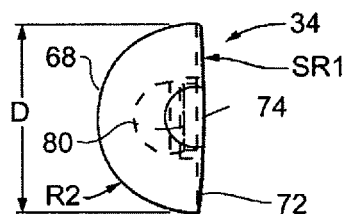


Fig. 13

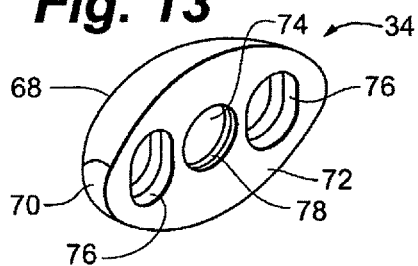


Fig. 14

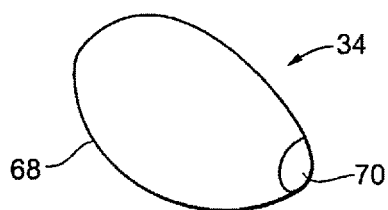


Fig. 15

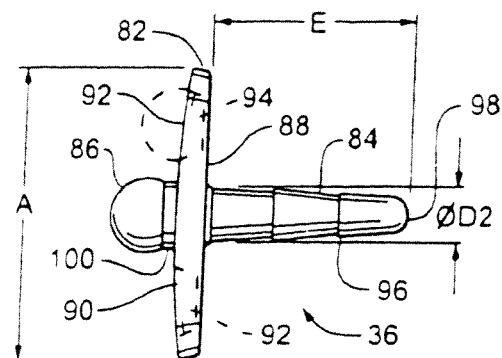


Fig. 16

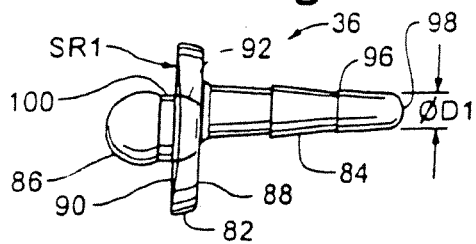


Fig. 17

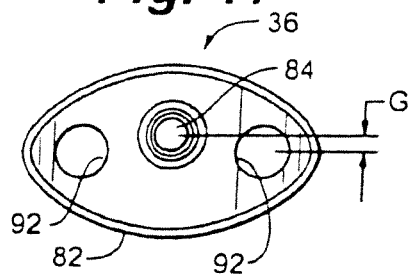


Fig. 18

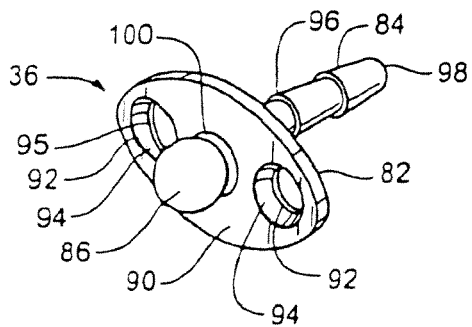


Fig. 19

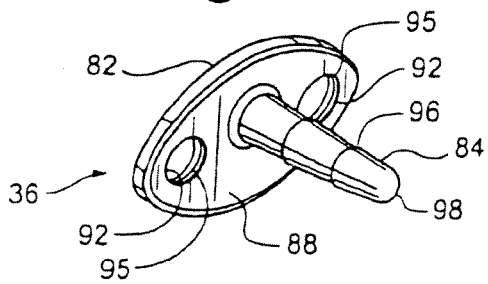


Fig. 20b

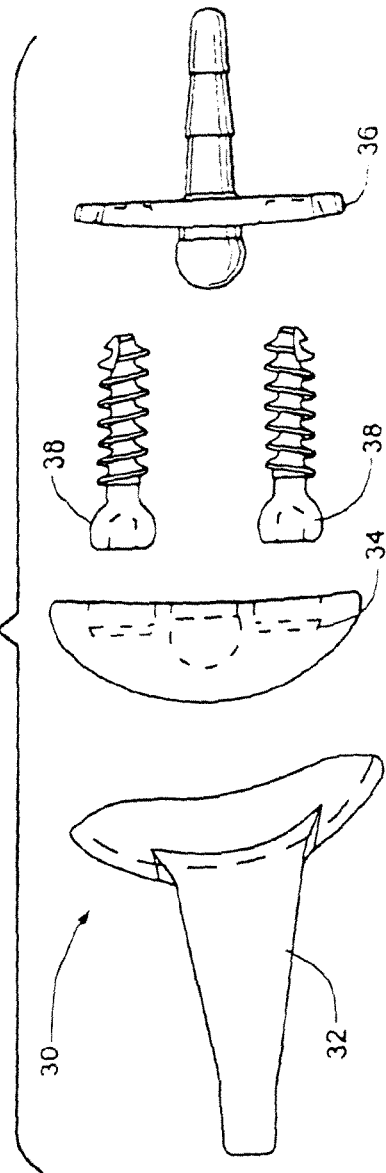


Fig. 20a

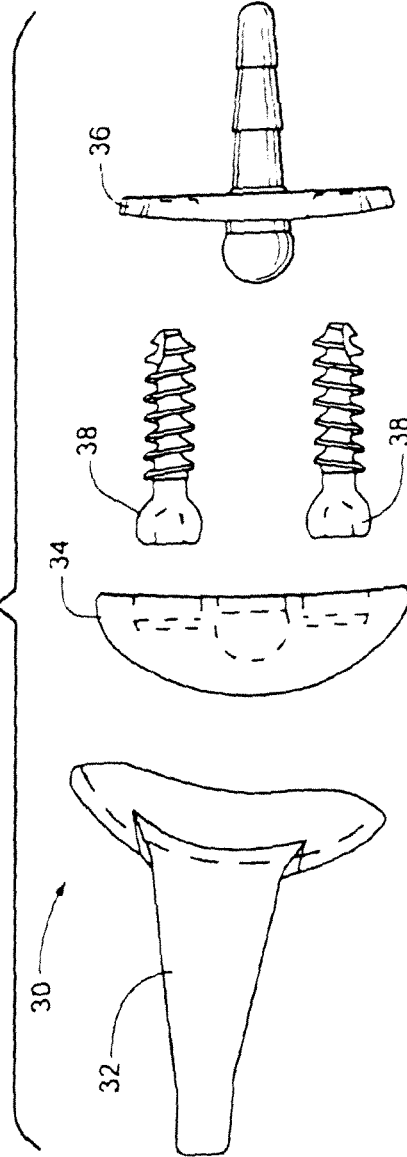


Fig. 21

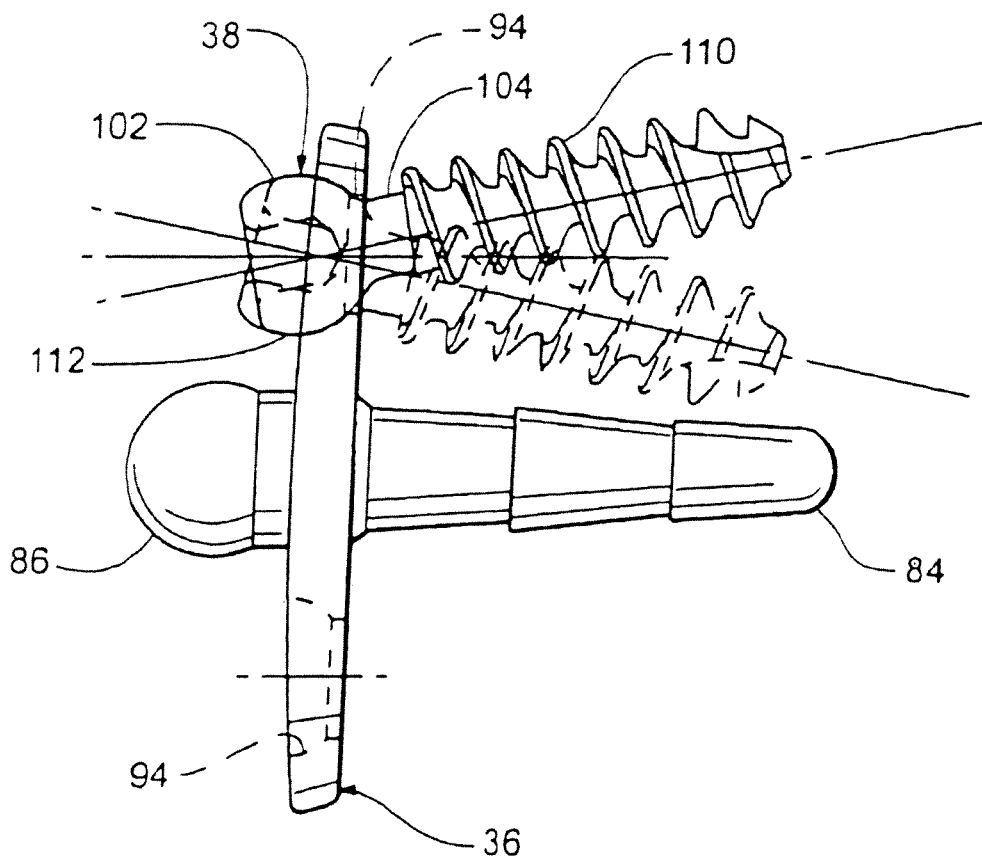


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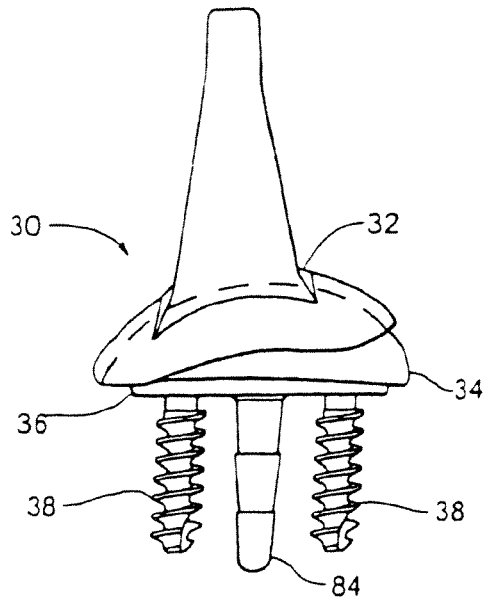


Fig. 23

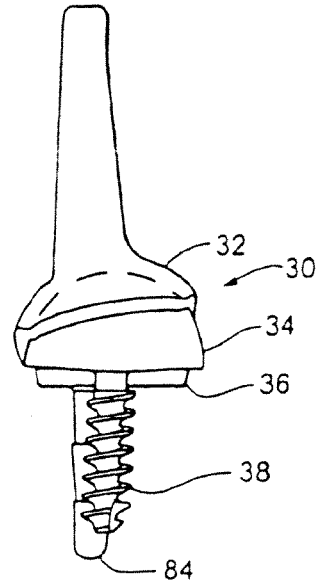


Fig. 24

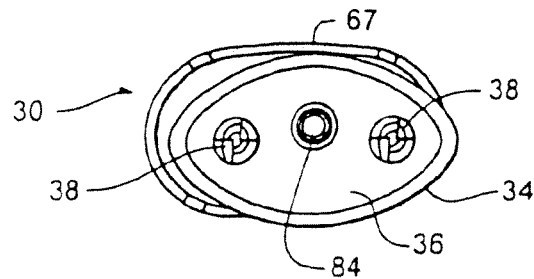


Fig. 25a

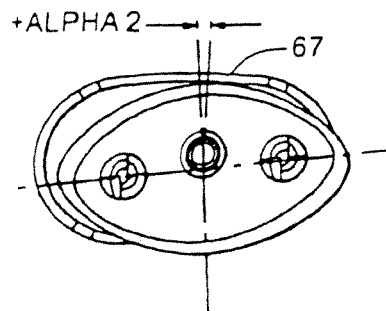


Fig. 25b

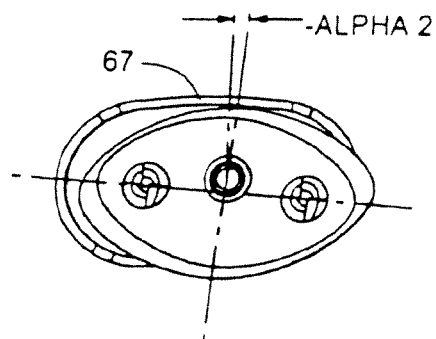


Fig. 26a

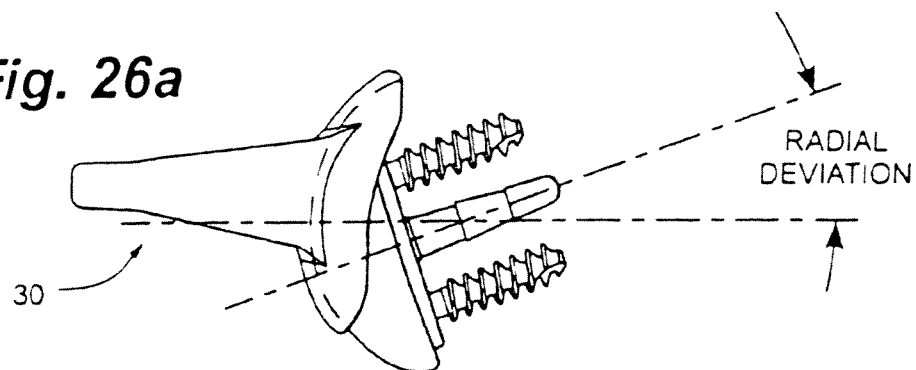


Fig. 26b

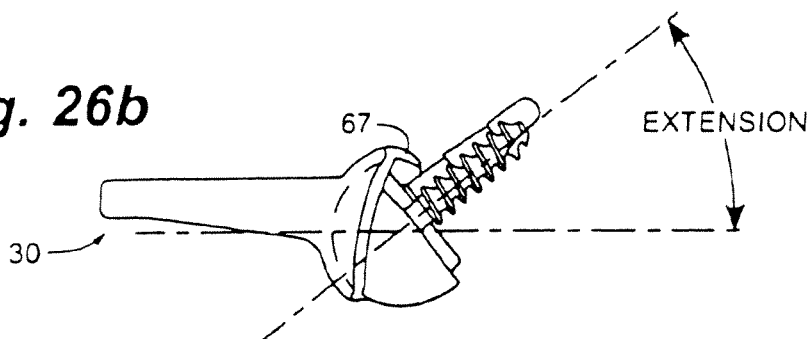


Fig. 26c

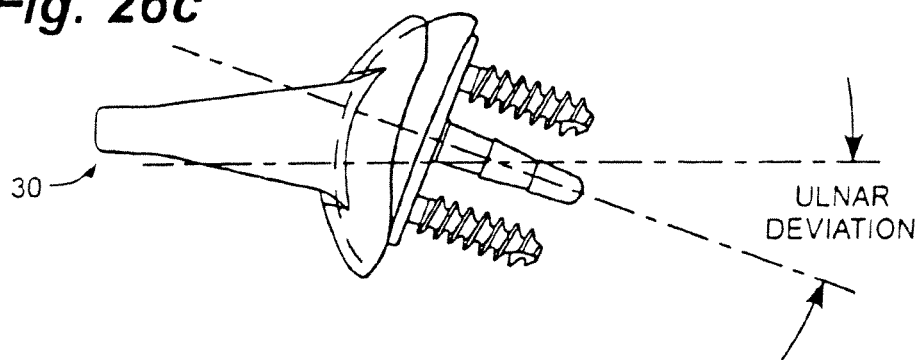


Fig. 26d

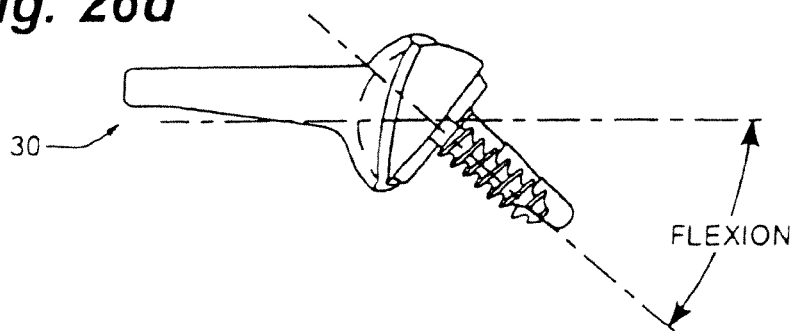
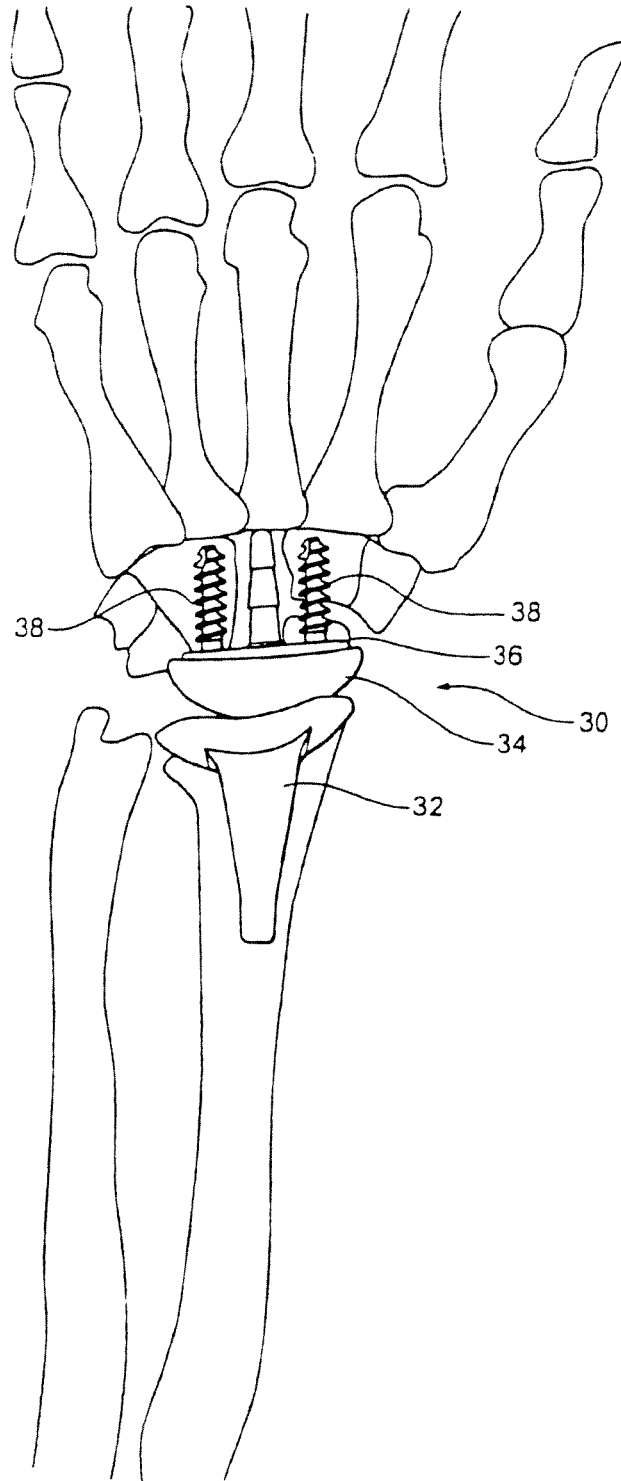


Fig. 27



PROSTHETIC WRIST IMPLANT**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. patent application Ser. No. 13/398,460, filed Feb. 16, 2012, which is a continuation of U.S. patent application Ser. No. 12/626,578, filed Nov. 25, 2009, now U.S. Pat. No. 8,118,876, which is a continuation of U.S. patent application Ser. No. 11/210,416, filed Aug. 24, 2005, now U.S. Pat. No. 7,628,819, which is a divisional of U.S. patent application Ser. No. 10/897,317, filed Jul. 22, 2004, now U.S. Pat. No. 7,625,408, which claims the benefit of U.S. Provisional Patent Application No. 60/489,037, filed Jul. 22, 2003, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The invention relates to prosthetic orthopedic implants. More particularly the invention relates to a prosthetic orthopedic wrist implant for prosthetic replacement of a damaged, diseased or degenerated natural wrist joint.

BACKGROUND

Orthopedic replacement of damaged or degenerated natural wrist joints is well known in the orthopedic arts. Prior to the introduction of prosthetic joint replacement for the wrist, individuals suffering from a joint disease in the wrist such as radio-carpal arthritis were often surgically treated by a fusion procedure. Fusion involves repairing the injured wrist joint structures with a fixed plate or rod that stiffens the wrist. That is, the joint is fixed in position by a device that allows no movement of the wrist. While this was an improvement over a diseased or injured wrist joint it is clearly unsatisfactory.

Existing orthopedic prostheses for wrist joint implantation have a number of limitations. Currently, most prosthetic wrist implants provide the patient with only limited functionality of the wrist, otherwise the implant becomes unstable. The natural wrist is astonishingly flexible in its freedom of motion. If a prosthetic wrist implant does not provide sufficient motion in flexion, extension, radial deviation, or ulnar deviation, the patient may have difficulty performing many of the normal tasks of daily living. Ideally, after implantation of a wrist prosthesis, the wrist will have a range of motion equal to or at least approaching that of a natural wrist joint.

An important requirement for prosthetic wrist implants is to have an extremely secure attachment between the implant and the bones. Separation of the prosthetic wrist implant from the bones to which it has been secured can be a serious complication requiring a repeat surgical procedure to make repairs. Failure of the attachment between the wrist prosthesis and the bones to which it is attached will cause further damage to the bones in some circumstances, making it difficult or impossible to treat the wrist even with a replacement implant. Prosthetic wrist implants currently in use generally require resection of the peripheral rim of the distal radius with its important ligaments and soft tissue attachments. The loss of these ligamentous attachments tends to create instability (looseness) of the prosthetic wrist. To compensate for this instability, a more involved surgical procedure must be performed to make reattachments of the soft tissue to the bone.

In addition, some currently available prosthetic wrist implants require the resection of a substantial amount of bone from the carpal bone structures. This substantial resection relocates the normal wrist centers of rotation (or motion) and

relocation of the centers of wrist rotation interferes with normal function of the wrist extensor and flexor tendons, alters tendon moment arms and, as a result, limits and weakens movement of the wrist in extension and flexion. Further, if a patient later needs another procedure at the same joint revision options are limited if excessive tissue has been resected.

Another shortcoming of existing prosthetic wrist implants is the limitation of torsional movement of the wrist related to the elbow. The healthy hand and wrist are able to rotate about an axis generally parallel to that of the long axis of the forearm, both because of the rotation of the radius and the ulna about one another, and because of the rotation of the natural wrist bones with relation to the radius and the ulna. Currently available prosthetic wrist implants typically involve the secure attachment of a proximal component of the wrist implant to the distal end of the radius and a distal component to the carpus with fixed planes of motion that result in a loss of torsional range of motion. In addition, if the forces involved in torsional movement of the wrist are limited by the implant as with current designs, those forces are transferred to the bone-implant interfaces at the radius and the carpus, increasing the risk of the implant loosening, and contributing to implant failure.

Further, in some wrist implant designs, a single stem extends through the carpus and into one or more of the metacarpals. The distal component of these wrist implants tends to erode through the metacarpal bone and create instability of the carpal attachment. Consequently the distal component of the implant may loosen or fracture where the implant enters the bones of the hand. In addition, in the normal wrist there is some freedom of motion between the carpals and the metacarpals and a stem passing through the carpals and into the metacarpals limits that freedom of motion resulting in less than ideal function of the wrist after implantation.

In addition, it has been found that implants that allow metal to metal contact between the radial and carpal components tend to cause shedding of metal particles that may migrate into surrounding tissues and may cause tissue necrosis and consequent implant failure and other complications.

Thus, it would be valuable to provide an improved orthopedic wrist implant that would provide a range of motion simulating the natural wrist's range of motion as closely as possible. In addition, it would be desirable if a prosthetic wrist implant would provide an improved torsional range of motion and reduce the effect of torsional forces on the bone-implant interface. It would further be desirable that a prosthetic wrist implant provide a secure, strong, and stable attachment to the surrounding bones in order to provide a wrist implant that would have low complications related to implant loosening. Further, it would be beneficial to preserve the peripheral rim of distal radius as well as the sigmoid notch of the distal radius where it articulates with the head of the ulna. It would be preferable to avoid metal-to-metal contact between the radial and carpal components.

SUMMARY OF THE INVENTION

The prosthetic wrist implant of the present invention solves many of the above limitations and problems related to wrist implant failure. The wrist implant of the present invention requires little or no resection of the distal radius and minimal resection of the carpal bones of the wrist. The implant is available in left and right hand configurations with geometrically scaled sizes that approximate the anthropomorphic sizes of different radio-carpal joints. The wrist implant generally includes a radius portion, a carpal portion and a carpal ball. The radial component of the prosthetic wrist implant is

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designed much like a surface replacement arthroplasty (SRA) in that it seats against the scaphoid and lunate fossae and preserves the peripheral rim of the distal radius with its important ligamentous and soft tissue attachments. This configuration requires minimal or no resection of the distal radius and preserves the sigmoid notch and articulation of the distal radius with the head of the distal ulna.

The carpal portion of the wrist implant is a low-profile design that minimizes the amount of bone resection and does not interfere with the normal function of the wrist extensor and flexor tendons. The carpal portion of the wrist implant may include a central stem for insertion into the capitate bone. The carpal portion accommodates two carpal screws for fixation to the scaphoid and hamate bones within the distal carpal row.

A carpal ball component preferably acts as an intercalated segment that articulates with both the radius and carpal portions of the implant. The primary articulation occurs with the radial component. The primary articulating surfaces may be ellipsoidal and toroidal and act along two perpendicular axes of rotation. The first axis lies in the coronal plane and the second axis lies in the sagittal plane thus permitting motion in flexion-extension and radial-ulnar deviation. The concavity of the radial portions' articular geometry resists ulno-volarly directed forces that can cause excessive wear and implant subluxation or dislocation.

In one embodiment a secondary articulation of the carpal ball component occurs with a carpal plate. This articulation is rotational and occurs about an axis aligned generally parallel with the longitudinal axis of the third metacarpal bone. This additional degree of freedom diverts torsional forces from the bone implant interfaces, thus reducing the risk of implant loosening and lessening the risk of implant failure. This additional degree of freedom of movement also compensates for potential misalignment of the implant due to advanced deformity of the injured wrist caused, for example, by rheumatoid or degenerative arthritis.

The interface between the ellipsoidal carpal ball and the toroidal radial component allows flexion-extension and radio-ulnar motion to occur about different axes of rotation. This allows for a hinge like motion dorso-palmarly and a gliding motion radio-ulnarly closely approximating natural joint kinematics.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a prosthetic wrist implant in accordance with the present invention;

FIG. 2 is a perspective view of the prosthetic wrist implant from a reverse angle to that of FIG. 1;

FIG. 3 is an exploded view of the prosthetic wrist implant;

FIG. 4 is a exploded perspective view of the prosthetic wrist implant from a reverse angle to that of FIG. 3;

FIG. 5 is a plan view of a radius component in accordance with the present invention;

FIG. 6 is an elevational view of the radius component in accordance with the present invention;

FIG. 7 is a perspective view of the radius component;

FIG. 8 is a second perspective view of the radius component;

FIG. 9 is a plan view of a carpal screw in accordance with the present invention;

FIGS. 10a and 10b are perspective views of two carpal screws in accordance with the present invention;

FIG. 11 is a plan view of a carpal ball in accordance with the present invention with phantom lines depicting internal structure;

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FIG. 12 is an elevational view of the carpal ball with phantom lines depicting internal structure;

FIG. 13 is a perspective view of the carpal ball;

FIG. 14 is a second perspective view of the carpal ball in accordance with the present invention;

FIG. 15 is a plan view of a carpal plate in accordance with the present invention;

FIG. 16 is an elevational view of the carpal plate in accordance with the present invention;

FIG. 17 is an end view of the carpal plate in accordance with the present invention;

FIG. 18 is a perspective view of the carpal plate in accordance with the present invention;

FIG. 19 is a perspective view from a second angle of the carpal plate in accordance with the present invention;

FIGS. 20a and 20b are exploded plan views showing the right and left hand configurations of the prosthetic wrist implant;

FIG. 21 is a plan view showing the articulation of one embodiment of a carpal plate and carpal screw in accordance with the present invention;

FIG. 22 is a plan view of the articulated parts of a prosthetic wrist implant;

FIG. 23 is an elevational view of the articulated parts of the prosthetic wrist implant;

FIG. 24 is an end view of the articulated parts of the prosthetic wrist implant;

FIGS. 25a and 25b depict the tertiary articulation of the carpal plate and carpal ball in accordance with one embodiment of the present invention;

FIGS. 26a-d depict the radial deviation, extension, ulnar deviation, and flexion of the primary articulation of an embodiment of the present invention; and

FIG. 27 is a schematic of the prosthetic wrist implant as implanted in a human wrist.

DETAILED DESCRIPTION OF THE DRAWINGS

A wrist implant 30 of the present invention generally includes radius component 32, carpal ball 34, carpal plate 36 and one or more carpal screws 38. Referring to FIGS. 1-4 radius component 32 articulates with carpal ball 34 via a primary articulation 40. Carpal ball 34 articulates with carpal plate 36 via secondary articulation 42 as best seen in FIG. 25. Carpal screws 38 articulate with carpal plate 36 via tertiary articulation 44, as best seen in FIG. 21.

Referring, in particular, to FIGS. 5-8, radius component 32 generally includes intra-medullary stem 46 and articular cup 48. In one embodiment, intra-medullary stem 46 is generally quadrilateral in cross-section and tapers from broad at a first end 50 to narrower at second end 52. Preferably, intra-medullary stem 46 and articular cup 48 are formed, cast or machined as an integral unit from a single piece of material. The juncture 54 between intra-medullary stem 46 and articular cup 48 is tapered in a fillet 56. Each corner 58 of intra-medullary stem 46 is radiused, beveled or chamfered. Intra-medullary stem 46 further defines rounded end 60 and a straight portion 62. Intra-medullary stem 46 also defines a stem thickness D. Intra-medullary stem 46 has a smooth continuous surface throughout and may be surface treated to encourage osseointegration. Thus, stem geometry emulates the intra-medullary contour of the distal radius. The smooth continuous surface of intra-medullary stem 46 means that medullary stem 46 lacks sharp corners or any significant discontinuities. The smooth continuous surface of intra-med-

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ullary stem **46** may include roughening of texture to encourage osseointegration while still retaining a smooth continuous shape.

Articular cup **48** is generally toroidal in shape and has a major dimension A and a minor dimension C. Articular cup **48** defines a generally toroidal concave articular surface **64**. Articular surface **64** preferably has two perpendicular axes, one axis of rotation and one instantaneous center, which lie in generally coronal and sagittal planes. Articular surface **64** defines two radii, a major radius, R1 and a minor radius R2. Major radius R1 and minor radius R2 may be selected to emulate the curve traced by the proximal portion of the scaphoid-lunate complex in the normal articulation of the human wrist as is clearly seen in FIG. 26. Articular cup **48** further includes cup wall **66**. Cup wall **66** is preferably of generally uniform thickness. Cup wall **66** is desirably curved to conform to the curvature of the scaphoid and lunate fossae of the distal end of the radius. Thus, the curvatures of articular surface **64** have generally shorter radii than does the exterior of cup wall **66**. Articular cup **48** further defines dorsal and volar cutouts **67**. The surface at dorsal and volar cutouts **67** is highly polished to facilitate the excursion of the flexor and extensor tendons and other soft tissues thereover. Dorsal and volar cutouts **67** also maximize range of motion in flexion and extension without metal to metal impingement of the radial and carpal components.

Articular surface **64** is, desirably, precision machined and highly polished for articulating with carpal ball **34**. Radius component **32** is preferably fabricated from cobalt chrome-molybdenum alloy material. The juncture between intramedullary stem **46** and articular cup **48** is angled to approximate the anatomical volar tilt and ulnar inclination angles of the distal radius. The articular surface **64** of the articular cup **48** is angled volarly and ulnarly. Ulnar inclination may be about twenty to twenty two degrees and volar tilt may be about ten to twelve degrees.

Intra-medullary stem **46** is offset in the anterior-posterior and lateral planes to align the articular cup **48** to seat against the lunate and scaphoid fossae and preserve the distal ulna. The intra-medullary stem **46** may be coated with a commercially pure titanium plasma coating to promote osseointegration.

Referring in particular to FIGS. 11, 12, 13 and 14, carpal ball **34** is generally ellipsoidal in shape. Carpal ball **34** has a convex articular surface **68**. Convex articular surface **68** may be shaped to generally match articular surface **64** of articular cup **48** to provide a close sliding fit therewith. Carpal ball **34** defines slightly flattened but still rounded articular ends **70**. Convex articular surface **68** has a major radius R1 and a minor radius R2 generally matching, respectively, those of articular cup **48**. Carpal ball **34** also has a back surface **72**. Back surface **72** is curved along a relatively flat secondary spherical radius SR1. Back surface **72** further defines socket **74**, and, preferably, two oval excavations **76**. Socket **74** includes rim **78** and spheroidal portion **80**. Socket **74** is, desirably, generally spherical in shape having a rim **78** that is of a lesser diameter than spheroidal portion **80**.

Carpal ball **34** has a major dimension B and a minor dimension D. Carpal ball **34** also presents a major curvature and a minor curvature.

Preferably, there are two oval excavations **76** on back surface **72**. Oval excavations **76** are of an oval, ellipsoidal, arcuate or racetrack shape and of a generally uniform depth. Oval excavations **76** may be arcuate centered about socket **74**.

Carpal ball **34** is made from ultra high molecular weight polyethylene (UHMWPE) or another self lubricating material. UHMWPE has the advantage of providing a thermal

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break as well as minimizing wear on the other articular components. However metals or other materials may also be utilized. Carpal ball **34** may be machined, molded or formed by other techniques known to the art.

In another embodiment of the invention, articular cup **48** defines a generally toroidal concave articular surface **64** that allows slight play between articular surface **64** and convex articular surface **68**. In this embodiment, carpal ball **34** has a convex articular surface **68** that tapers slightly toward articular ends **70**. Convex articular surface **68** is shaped to match articular surface **64** of articular cup **48** to provide a close sliding fit therewith near the center of convex articular surface **68** but a looser sliding fit near articular ends **70**. It is important to note that the ellipsoidal geometry of the carpal ball **34** demonstrates a line-to-line contact of the carpal ball **34** and the articular Clip **48** in the anterior-posterior and lateral planes.

Referring in particular to FIGS. 15-19, carpal plate **36** generally includes plate **82**, carpal stem **84** and ball **86**.

Plate **82** includes buttress surface **88**, secondary articular surface **90** and defines screw holes **92**. Buttress surface **88** is preferably substantially flat. Secondary articular surface **90** is curved along spherical radius SR1 to match back surface **72** of carpal ball **34**. This facilitates better wear characteristics between carpal ball **34** and carpal plate **36** by reducing peripheral stress risers that may cause fretting of the carpal ball **34** and, possibly, debris generation. Screw holes **92** pierce plate **82**, preferably on opposite sides of ball **86**. Screw holes **92** include spheroidal countersink **94** and cylindrical rim **95**. Plate **82** is generally elliptical in shape as best seen in FIG. 17. The periphery of plate **82** is radiused at the edge of secondary articular surface **90**. Distal to the radiused edge the periphery of plate **82** is drafted to optimize articular contact area and avoid metal to metal contact at the extremes of range of motion and axial rotation.

Carpal stem **84** extends outwardly from bone interface surface **88** a distance E and has a diameter D2 at its proximal end, having a smooth or stepped taper to D1 at its distal end. Preferably, carpal stem **84** is generally perpendicular to plate **82**. Carpal stem **84** may include retaining ridges **96** and hemispherical end **98**. Referring particularly to FIGS. 16-17 and 19, note that carpal stem **84** may be offset from a line connecting screw holes **92** a distance G. Carpal stem **84** is of a length E such that it does not extend into or beyond the carpal-metacarpal interface.

Ball **86** is secured against secondary articular surface **90**. Preferably, plate **82**, carpal stem **84** and ball **86** are integrally formed or machined from a single piece of material. Ball **86** is spheroidal in shape and has a diameter larger than that of ball support **100**. Ball **86** is located generally between screw holes **92** to fall, when implanted, along an axis generally aligned with the third metacarpal. The diameter of ball **86** is equal to or slightly smaller than spheroidal portion **80** of socket **74** of carpal ball **34**.

Carpal plate **36** is advantageously fabricated from cobalt chrome-molybdenum alloy material. Buttress surface **88** and carpal stem **84** may be coated with commercially pure titanium plasma coating to promote osseointegration. As mentioned above, carpal stem **84** is dorsally offset from screw holes **92** to accommodate the arch of the carpus. Secondary articular surface **90** and ball **86** along with ball support **100** are precision machined and highly polished to allow smooth articulation with carpal ball **34**.

Referring particularly to FIGS. 9-10 and 21, carpal screws **38** generally include head **102** and shaft **104**. In one embodiment, head **102** is spheroidal in shape and defines flat face **106** and driver interface **108**. Driver interface **108**, as depicted,

accepts a standard 2.5 mm hex screwdriver but can be formed to interface with any screwdriver known in the art. Carpal screws **38** are selected of a length so that carpal screws **38** do not cross the carpal-metacarpal joint when implanted.

Shaft **104** may be of a length and diameter desired within the above limitations and has a cancellous thread form **110** for optimum fixation with the carpal bones of the wrist. An unthreaded portion of shaft **104** provides clearance so that carpal screws **38** may conically rotate relative to carpal plate **36**. Spheroidal portion **112** of head **102** allows for ideal screw angulation as determined by a surgeon during the surgical procedure. Preferably carpal screws **38** are placed into the scaphoid and hamate bones of the carpus. The radius of spheroidal portion **112** is equivalent to that of spheroidal countersink **94** of carpal plate **36**. Spheroidal portion **112** stands proud of secondary articular surface **90** of carpal plate **36** when implanted.

Carpal screws **38** are fabricated from cobalt chrome-molybdenum alloy material. Cancellous thread form **110** is designed to provide a secure grip in the cancellous and cortical portions of the carpal bones. Carpal screws **38** may be fluted for self-tapping application. The length of carpal screws **38** may vary as needed to accommodate patient anatomy but advantageously should not pass into or through the carpal-metacarpal joint. Carpal screws **38** may be manufactured to the standards of ISO 5835.

In operation, wrist implant **30** is implanted in the wrist of a patient to replace damaged or degenerated wrist structure as depicted in FIG. **27**. In general, radius component **32** is implanted in the distal end of the radius without the need to perform resection of the distal portion of the radius. The distal radius cartilage and any heterotopic bone or osteophytes are removed from the scaphoid and lunate fossae at the end of the distal radius, but the bony structures of the distal radius preferably are not resected at all. A starter hole is drilled in the distal radius generally parallel to the long axis of the radius. This drilled hole provides a starting point for the use of a series of progressively larger broaches until the cavity in the distal radius is large enough to allow full seating of the radius component **32**. The cavity is broached until it is large enough to provide a press fit for intra-medullary stem **46**.

Prior to resecting the carpus, a guide (not shown) is used to measure the carpal resection. The bones of the carpus are resected across the proximal carpal row. Preferably, the carpal resection is performed along a plane generally perpendicular to the long axis of the radius. The lunate, triquetrum and proximal scaphoid and the head of the capitate may be resected. However, preferably only the lunate and the proximal pole of the scaphoid are removed. After the carpal bones are resected, a second guide (not shown) is temporarily attached to the carpal bones in order to allow for accurate drilling into the center of the capitate to provide a starter hole for a cavity for carpal stem **84**. In addition, two starter holes are created to accommodate the placement of carpal screws **38** into the carpus. The radius component **32**, carpal ball **34** and carpal plate **36** are then articulated. To articulate carpal ball **34** to carpal plate **36**, carpal ball **34** is pressed against ball **86** so that socket **74** overlies ball **86**. Force is then applied so that UHMWPE of carpal ball deforms around ball **86** and resiliently snaps back to grip ball **86**.

The foregoing provides an overview of the surgical implantation procedure. A detailed description of the surgical procedure can be found below.

Once implanted, radius component **32** articulates with carpal ball **34** to provide a simulation of natural motion of the wrist. The toroidal shape of articular cup **48** and ellipsoidal shape of convex articular surface **68** interact to provide a free

and natural primary articulation of wrist implant **30**. Primary articulation **40** preferably allows a minimum radial deviation of about twenty degrees and an ulnar deviation of twenty degrees for a total of about forty degrees. Primary articulation **40** further allows extension of the wrist at least forty degrees and flexion of the wrist at least forty degrees for a total of about eighty degrees minimum. Note that the wrist implant **30** of the invention as depicted and disclosed herein permits much greater free movement of the wrist than these minimums. These minimum deviations have been found to provide a good range of motion for normal daily activities.

Thus, the motion of the implanted wrist implant **30** is generally hinged dorso-palmarly and gliding radio-ulnarly emulating normal joint kinematics. Flexion and extension occur about a first axis of rotation and radio-ulnar motion occurs about a second axis of rotation. In one embodiment of the invention, radius component **32** articulates with carpal ball **34** with a degree of incorporated laxity in the rotational degree of freedom. This incorporated laxity reduces torsional stresses that might otherwise be transferred to the bone-implant interfaces and tend to cause loosening of radius component **32** or carpal plate **36**.

In one embodiment of the invention, radius component **32** articulates with carpal ball **34** in radial-ulnar deviation, flexion-extension and also in a rotational degree of freedom. As discussed above, convex articular surface **68** may be generally ellipsoidally shaped to interface with the toroidal shape of articular surface **64** of articular cup **48** to provide a close sliding fit therewith near the center of convex articular surface **68** but a looser sliding fit near articular ends **70**. This interface allows carpal ball **34** to "wobble" relative to articular cup **48** thus providing limited rotational movement about an axis generally along the long axis of the radius. The use of ellipsoidal-toroidal geometry demonstrates constant line to line contact in the anterior-posterior and lateral planes.

Carpal ball **34** articulates with carpal plate **36** at secondary articulation **42**. Socket **74** is an interference fit with ball **86**. This secondary articulation **42** provides for motion about a rotational axis generally parallel to the long axis of the third metacarpal. Secondary articulation **42** provides for more natural wrist motion and lessens the risk of loosening of carpal plate **36** from the carpus and radius component **32** from the radius by minimizing the application of torsional forces to the bone-implant interfaces. The spheroidal head **102** of carpal screws **38** limits secondary articulation **42** by the interaction of oval excavation **76** with head **102** of carpal screws **38**. Preferably, this limitation of movement is to about plus or minus five degrees or a total of about ten degrees.

Tertiary articulation **44** arises between the head **102** of carpal screws **38** and spheroidal countersink **94** in carpal plate **36** (FIG. **18**). Tertiary articulation **44** allows the surgeon to angle carpal screws **38** as desired for best fixation in bony structures while at the same time assuring that carpal screw **38** will have a tight interface with spheroidal countersink **94**. Tertiary articulation preferably allows about ten to fifteen degrees of variation in the angle of carpal screws in any direction from a perpendicular to buttress surface **88**.

Surgical Technique

A pre-operative assessment using an x-ray template should be made to approximate the size of the wrist implant **30**. A carpal cutting guide may be provided with a small, medium, and large flange that can be fitted over the guide handle and tightened in place. Based upon an x-ray assessment, the appropriate size carpal resection guide should be assembled. The guide flange of the carpal resection guide is placed against the distal surface of the radius in the lunate fossa and the amount of carpal bone resection required is determined.

Dorsal Longitudinal Incision

A dorsal incision is made in line with the third metacarpal centered directly over Lister's tubercle.

Extensor Retinaculum Exposure

The extensor retinaculum is exposed and reflected from radial to ulnar from the first extensor compartment to the fifth or sixth extensor compartment.

A midline incision over the fourth extensor retinaculum is acceptable in "dry" rheumatoids and post-traumatic or osteoarthritic wrist. The distal part of the extensor retinaculum can be used to reinforce the dorsal wrist capsule in synovitic rheumatoid wrist.

Synovectomy of Extensor Tendons

After exposure, a synovectomy of the extensor tendons is performed as necessary.

Exploration of Carpals

A rectangular shaped wrist carpal flap is reflected from proximal to distal to expose the proximal and distal carpal rows. Synovectomy of wrist is performed as required.

Carpal Resection

A carpal resection guide (not shown) is set across the wrist joint for resection of the proximal carpal row. The length of the resection is determined by placing the flange against the distal radius/lunate fossae without carpal dislocation. The lunate, triquetrum, proximal scaphoid, and head of the capitate are resected.

Proximal Guide Placement

A proximal radial guide (not shown) is inserted to determine the resection of heterotopic bone and osteophytes from the distal radius. The convex side of the guide is placed against the concave surface of the distal radius. The wrist is flexed to allow best alignment of the proximal guide.

Drilling of the Radius

A radial template (not shown) in small, medium, and large sizes with left and right hand configurations is utilized. The proper template to be used is based upon the preoperative assessment. The distal face of the template represents the distal extent and peripheral coverage of the radial implant component. A drill hole in the template establishes a starting location for a broach. A 3.5 mm drill is inserted into the hole and a hole is drilled to a depth of 20-30 mm. The drill should be aligned along the long axis of the radius in both anterior/posterior and lateral planes. Biplanar fluoroscopic X-ray imaging confirmation of guide placement is important to insure proper alignment prior to broaching.

Preparation of the Radius

Based upon the pre-operative assessment of the implant size, the distal radius is broached with increasing sized broaches to allow full seating of the radius component **32**. Care should be taken to ascertain that the handle of the broach is aligned with the long axis of the radius. The broach may need to be withdrawn occasionally to clean the teeth and clear the intra-medullary cavity of debris.

The goal is to remove no more subcortical bone than necessary to allow prosthesis insertion (resection of the distal radius, as is performed with other wrist prostheses, is not required or recommended).

Radial Trial Placement

A trial radius component **32** is inserted into the prepared canal and impacted. The fit of the radius component **32** against the scaphoid and lunate fossae is evaluated. If the fit is satisfactory, the trial radius component **32** is removed by engaging the extraction holes with a clamp. In some situations, it may be necessary to use a small burr to contour the cartilage of the radius to achieve a desired fit. The radial template (not shown) can be used as a guide to approximate the amount of burring needed.

Carpal Templating

A carpal template (not shown) for locating the carpal plate **36** fixation holes for receiving carpal screws **38** is placed against the distal carpal resection site. A central hole in the template is aligned with the center of the capitate. Biplanar imaging can be used to confirm proper alignment. Using k-wire(s), the distal pole of the scaphoid may be temporarily fixed to the capitate to facilitate scaphoid screw preparation and insertion.

Carpal Drilling

A 3.5 mm drill is inserted into the central hole and a hole is drilled through the capitate but not into the second or third metacarpal. Imaging can be used to confirm proper alignment. The hole is drilled to depths appropriate for the size of the implant utilized. The drill bit is preferably disconnected from the drill driver and left in place facilitate drilling of the radially and ulnarly positioned screw sites. A 0.62 k-wire is inserted into the ulnarly located hole of the carpal template. The k-wire can be angulated within the carpal template to achieve proper placement within the distal carpal row. The k-wire is drilled to the depth of the screw length determined pre-operatively and the drill is removed from the k-wire. Imaging can be performed to evaluate placement. The same procedure is repeated for the radially positioned hole of the carpal template. If the guide is aligned correctly, the k-wires and drill bit should form a "W" shape within the distal carpal row.

Carpal Trial Placement

The stem of the trial carpal plate **36** is inserted into the capitate verifying that the dorsal aspect of the trial component is positioned correctly. Note: the stem is offset dorsally from the screw holes to accommodate the natural arch of the carpus. The trial carpal plate is seated against the resection using a carpal impactor (not shown). Placement is confirmed with imaging.

Radial Trial Placement

The trial radial component **32** is placed into the radius and tapped into place using an impactor (not shown).

Carpal Ball Trial Placement

A carpal ball **34** trial component is placed over the trial carpal plate **36** and the joint is reduced. Note: preferably the carpal balls **34** are available in two thicknesses, neutral and plus.

Range of Motion Assessment

The joint is articulated and joint stability and motion are assessed. There should be slight distraction across the implant interface of no more than 2-3 mm. The cut generated by the carpal resection guide is designed for the neutral thickness of the carpal ball **34**. However, if there appears to be too much joint laxity, the plus thickness carpal ball **34** can be used. It is very important that the proper carpal ball **34** size is selected because it is difficult to disarticulate the carpal ball **34** from the carpal plate **36** once assembled. Full range of motion without impingement or instability should be present. Once range of motion is satisfactory, all trial components should be removed.

Component Placement

The definitive radius component **32** and carpal plate **36** and carpal ball **34** are now inserted. The radius component **32** is designed for press fit, however bone allograft can be added if there is osteopenia or osteoporosis and to adjust seating of the radius component **32** to make up for any joint laxity. The radius component **32** is tapped firmly into place. Optionally, bone cement can be used to secure the radius component **32**. The carpal plate **36** is inserted next. It is aligned with the centering hole in the capitate and pushed or tapped into place. The self-tapping radial and ulnar cancellous carpal screws **38**

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are inserted through the carpal plate 36 and into the holes created by the k-wires. The screws are now tightened into place.

The carpal ball 34 is snapped into place using the carpal ball impactor (not shown). The radius component 32 and carpal plate 36 are reduced and articulated. Any temporary scaphoid to capitate k-wires are removed. If indicated, bone graft from excised carpal bones can be used to fuse together the distal carpal bones.

If the carpal ball 34 needs to be removed, care must be taken to not damage the polished secondary articular surface 90 of the carpal plate 36. Removal may be necessary to adjust joint tension or laxity or to modify screw length. This can be accomplished by drilling a small hole in the radial and ulnar flattened articular ends 70 of the polyethylene and engaging the holes created with a bone reduction forceps and prying in a radial or ulnar direction to disengage the snap fit assembly. Repair of Dorsal Capsule & Closure

The dorsal capsule is repaired back to the distal radius. If necessary drill holes are made in the dorsal, and distal radius. A tight capsule closure is performed with the wrist in extension (20°). A distal third of extensor retinaculum is added to reinforce capsular closure. Lastly, the extensor retinaculum is closed.

The present invention may be embodied in other specific forms without departing from the central attributes thereof, therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than the foregoing description to indicate the scope of the invention.

What is claimed is:

1. An implantable wrist prosthesis for implantation in a wrist, the wrist including a distal end of a radius presenting a substantially concave end surface contour and a carpus, the implantable wrist prosthesis comprising:

a radius component comprising an articular receiver and an intramedullary stem extending from the articular receiver, the articular receiver having an inner receiver wall and further having an outer receiver wall adapted to substantially conform to the end surface at the distal end of the radius;

a carpal plate having a hole and a bone interface surface and a spheroidal protrusion extending outwardly from a side opposite the bone interface surface;

a first carpal screw positioned through the hole in the carpal plate, wherein with the carpal plate secured to the carpus and the screw through the hole in the carpal plate, a portion of a head of the first carpal screw stands proud of the carpal plate; and

a carpal piece having a first articulation with the radius component and a second articulation with the carpal plate between a spheroidal cavity on the carpal piece and the spheroidal protrusion, wherein the carpal piece includes an excavation into which a screw head extends, the excavation having a perimeter that impinges on the screw head to limit the second articulation of the carpal piece and the carpal plate.

2. The prosthesis of claim 1, further comprising a third articulation between the hole of the carpal plate and a head of the first carpal screw, wherein the third articulation affords polyaxial rotation of the screw relative to the carpal plate.

3. The prosthesis of claim 2, wherein the polyaxial rotation allows for a screw angle of up to about 15 degrees in any direction from perpendicular with the carpal plate.

4. The prosthesis of claim 1, wherein the second articulation is limited to about 10 degrees, or less, total.

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5. An implantable wrist prosthesis for implantation in a wrist, the wrist including a distal end of a radius presenting a substantially concave end surface contour and a carpus, the implantable wrist prosthesis comprising:

a carpal plate having a hole and a bone interface surface and a spheroidal protrusion extending outwardly from a side opposite the bone interface surface;

a first carpal screw positioned through the hole in the carpal plate, wherein the carpal plate secured to the carpus and the screw through the hole in the carpal plate, a portion of a head of the first carpal screw stands proud of the carpal plate; and

a carpal ball articulated with the carpal plate, the carpal ball including a spheroidal cavity engaging the spheroidal protrusion through an interference fit, the articulation occurring between the spheroidal protrusion and the spheroidal cavity, the carpal ball including an excavation into which the screw head extends, the excavation having a perimeter that impinges on the screw head to limit the second articulation of the carpal piece and the carpal plate.

6. The prosthesis of claim 5, further comprising a radius component including an articular cup and an intramedullary stem extending from the articular cup, the articular cup having an inner cup wall and further having an outer cup wall that is convexly curved such that the outer cup wall is adapted to substantially conform to the concave end surface contour at the distal end of the radius.

7. The prosthesis of claim 5, wherein the first carpal screw includes a head, wherein the first carpal screw rotates polyaxially relative to the carpal plate with the head positioned within the hole.

8. The prosthesis of claim 7, wherein the polyaxial rotation allows for a screw angle of up to about 15 degrees in any direction from perpendicular with the carpal plate.

9. The prosthesis of claim 5, wherein the second articulation is limited to about 10 degrees, or less, total.

10. An implantable wrist prosthesis comprising:

a radius component, the radius component comprising an articular cup having an inner cup wall and further having an outer cup wall, and an intramedullary stem extending outwardly from the outer cup wall;

a carpal component including a hole and securable to a carpus;

a first carpal screw positioned through the hole in the carpal component positioned through the hole in the carpal component, wherein with the carpal component secured to the carpus and the screw through the hole in the carpal component, a portion of a head of the first carpal screw stands proud of the carpal component; and

a carpal ball articulated between the radius component and the carpal component, the carpal ball engaging into the inner cup wall and having at least two degrees of freedom relative to the articular cup, the carpal ball engaging the carpal component and having limited rotational freedom relative to the carpal component, the carpal ball engaging the carpal component via an interference fit between a generally spheroidal protrusion and a generally spheroidal socket, the carpal ball including an excavation into which the screw head extends, the excavation having a perimeter that impinges on the screw head to limit the second articulation of the carpal component and the carpal ball.

11. The prosthesis of claim 10, wherein the first carpal screw includes a head, wherein the first carpal screw rotates polyaxially relative to the carpal component with the head positioned within the hole.

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12. The prosthesis of claim **10**, wherein the second articulation is limited to about 10 degrees, or less, total.

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